epocal

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MAR 3 0 2010

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K092849 .

Summary Prepared: Sept 11, 2009

Submitted by:

Epocal Inc.
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Contact:

Roy Layer
Director of Quality Assurance and Regulatory Affairs.

5.1 Identification of the Device

Device Name: epoc® Blood Analysis System
Proprietary / Trade Name: epoc Blood Analysis System
Common Name: Portable Blood Analyzer
Classification Name: See Table 5.1 Below
Device Classification: See Table 5.1 Below
Regulation Number: See Table 5.1 Below
Panel: See Table 5.1 Below
Product Code: See Table 5.1 Below

Name	Class	Regulation Number	Panel	Product Code
Electrode Measurement, Blood-Gases (PCO2, PO2) and Blood pH	II	862.1120	Clinical Chemistry	CHL
Electrode, Ion Specific, Sodium	II	862.1665	Clinical Chemistry	JGS
Electrode, Ion Specific, Potassium	II	862.1600	Clinical Chemistry	CEM
Electrode, Ion Specific, Calcium	II	862.1145	Clinical Chemistry	JFP
Glucose	II	862.1345	Clinical Chemistry	CGA
Hematocrit	II	864.6400	Hematology	JPI

Figure 5.1 – Table - epoc™ Blood Analysis System with Blood Gas, Electrolytes and Metabolytes (BGEM) Test Card

5.2 Identification of the Predicate Device

i-STAT® Model 300 Portable Clinical Analyzer

5.3 Description of the New Device

The epoc System is a point-of-care device currently in use in hospitals. The epoc System was previously cleared for use with arterial and venous blood in 510(k) submissions K061597 and K090109. In this submission we are seeking clearance to use capillary blood specimens on the epoc System and to remove the limiting labeling regarding the glucose test using neonatal samples.

The epoc Blood Analysis System consists of three (3) components:

1. epoc Test Card
   The single use blood test card comprises a port for introduction of a blood sample to an array of sensors on a sensor module. The sensor module is mounted proximal to a fluidic channel contained in a credit-card sized housing. The card has an on-board calibrator contained in a sealed reservoir fluidically connected to the senor array through a valve.

2. epoc Card Reader
   The reader is a minimally featured raw-signal acquisition peripheral. The reader comprises a card orifice for accepting a test card, and a mechanical actuation assembly for engaging the test card after it is inserted into the card orifice. Within the reader's card orifice there is a bar code scanner, an electrical contact array for contacting the card's sensor module, and a thermal subsystem for heating the card's measurement region to 37°C during the test. The reader also comprises circuits for amplifying, digitizing and converting the raw sensor signals to a wireless transmittable Bluetooth™ format,

3. epoc Host
   The host is a dedicated-use Personal Digital Assistant (PDA) computing device with custom software that displays the test results. The reader and host computer together constitute all of the subsystems generally found in a traditional analyzer that operates on unit-use sensors and reagents

5.3.1 epoc Care-Fill Capillary Tube

The epoc Care-Fill Capillary Tube has been developed to introduce capillary samples into the epoc Test card. The epoc Care-Fill Capillary Tube is intended for use only with epoc Blood Analysis System and is the only method, other than using a syringe, to introduce samples into the epoc test cards.

5.4 Intended Use of the Device

The epoc System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous, or capillary whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

The BGEM test card panel configuration includes sensors for sodium (Na), potassium (K), ionized calcium (iCa), pH, pCO_2, pO_2, glucose (Gluc) and hematocrit (Hct).

Care-Fill Capillary Tubes are intended for use with the epoc Blood Analysis System and are used for the collection and dispensing of capillary blood samples with epoc Test Cards.

5.5 Comparison of Technological Characteristics To Predicate Device

	epoc Blood Analysis System			i-STAT Model 300			
510(k) #	K061597 and K090109			K001387			**Same / Different**
Item	Device			Predicate			
Intended use	The epoc Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of whole blood using the BGEM (Blood Gas Electrolyte Metabolyte), BGE (Blood Gas Electrolyte) and ABG (Arterial Blood Gas) test card panels.			The i-STAT Model 300 Portable Clinical Analyzer is intended to be used by trained medical professionals for use with i-STAT test cartridges and MediSense blood glucose test strips. i-STAT cartridges comprise a variety of clinical chemistry tests and test panels.			same
Where used	hospital			hospital			same
Measured parameters	pH, pCO_2, pO_2, Na, K, iCa, Gluc, Hct			pH, pCO_2, pO_2, Na, K, iCa, Gluc, Hct			same
Calculated parameters	TCO_2, HCO_3,BE,sO_2,Hgb			TCO_2, HCO_3,BE,sO_2,Hgb			same
Sample type	Venous, arterial and capillary whole blood			Venous, arterial and capillary whole blood			same
Reportable ranges	pH	6.5 – 8.0	pH units	pH	6.5 – 8.2	pH units	different
	pCO_2	5 – 250	mm Hg	pCO_2	5 – 130	mm Hg	different
	pO_2	5 – 750	mm Hg	pO_2	5 – 800	mm Hg	same
	Na	85 – 180	mmol/L	Na	100 – 180	mmol/L	different
	K	1.5 – 12	mmol/L	K	2.0 – 9.0	mmol/L	different
	iCa	0.25 – 4	mmol/L	iCa	0.25 – 2.5	mmol/L	different
	Glu	20 – 700	mg/dL	Glu	20 – 700	mg/dL	same
	Hct	10 – 75	%PCV	Hct	10 – 75	%PCV	same
	TCO_2	1 – 85	mmol/L	TCO_2	5 - 50	mmol/L	different
	HCO_3	1 – 85	mmol/L	HCO_3	1 – 85	mmol/L	same
	BE_{ecf}	-30 - +30	mmol/L	BE_{ecf}	-30 - +30	mmol/L	same
	BE_b	-30 - +30	mmol/L	BE_b	-30 - +30	mmol/L	same
	sO_2	0 – 100	%	sO_2	0 – 100	%	same
	Hb	3.3 – 25	g/dL	Hb	3 – 26	g/dL	same
Sample volume	Non volumetric over 90 µL			100µL			same
Test card	Unit-use card with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber			Unit-use cartridge with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber			same
Test card storage	Room temperature until expiry date			Storage at 2-8°C until expiry date including max 2 weeks at room temperature			different
Sensor array	A laminated foil sensor module			A micro-fabricated chip-set			different
Tests/sensor components	pH - PVC ion selective electrode pCO_2 -QH modified Severinghaus type pO_2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Glu - Enzymatic (glucose oxidase based), amperometric peroxide detection Hct – conductivity, gold electrodes			pH - PVC ion selective electrode pCO_2 - QH modified Severinghaus type pO_2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Glu – Enzymatic (glucose oxidase based), amperometric peroxide detection Hct – conductivity, gold electrodes			same same same same same same same same
Analyzer components	Two housings; 1 - The reader comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation			A single housing comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation			different same same same

	- mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers - MUX - A/D - Bluetooth stack for wireless transmission of digitized raw sensor signals to computing device - bar code scanner for acquiring card info - internal electronic reader self-test circuit 2 - The computing device comprising a PDA - microprocessor - memory - color LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via plug in plug-in power supply	- mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers - MUX - A/D - wire transmission of digitized raw sensor signals to computing subsystem in same housing - n/a - internal and external electronic self-test circuit - microprocessor - memory - monochrome LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via external power supply in downloader cradle	same same same same same same same same different different different same same different same same same
Measurement temperature	37°C	37°C	same
Measurement sequence	Calibrate test card-introduce sample-measure	Introduce sample-calibrate test cartridge-measure	different
Measurement time	35sec from sample introduction	130-200 sec from sample introduction	different
Error detection	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	same same same

Figure 5.2 – Table Comparing epoc Device Performance Characteristics With Predicate Device

In this 510(k) submission we demonstrate that the epoc System is substantially equivalent to the predicate device when using capillary blood. This submission also includes glucose data on neonatal capillary whole blood and therefore offers ground to remove the current labeling limitation on the epoc glucose test.

5.6 Summary of Non-Clinical Test Performance in Support of Substantial Equivalence

5.6.1 Equivalence of the epoc Test Results Between Samples Delivered from a Syringe Versus Samples Delivered from Care-Fill Capillary Tubes

Experiments were performed in house to demonstrate that the collection and delivery method using Care-Fill cap tubes yields test results equivalent with those where a syringe is used as a sample delivery method. This study was also used as the only opportunity to test the capillary delivery over extended ranges of the various analytes, as capillary samples are difficult to modify.

The table in Figure 5.3. below shows the results of a method comparison between the two means of sample delivery: X-syringe and Y-Care-Fill capillary tube.

	EPOC-CareFill vs EPOC-Syringe							
	pH	**pCO2**	**pO2**	**Na**	**K**	**Ca**	**Glu**	**Hct**
N	42	42	42	42	42	42	42	42
Sxx	0.004	0.8	3.1	0.5	0.06	0.018	4.7	0.41
Syy	0.005	1.4	2.5	0.7	0.10	0.019	4.0	0.60
intercept	0.446	3.8	0.4	2.7	0.06	-0.010	-2.5	1.6
slope	0.940	0.885	0.996	0.981	0.981	0.991	1.037	0.946
Syx	0.008	1.1	2.2	1.0	0.07	0.037	4.07	0.7
X min	6.721	14.0	22.7	102.5	1.2	0.389	16.0	10.5
X max	7.555	143.6	383.0	176.0	12.0	2.868	530.5	76.7
R^2	0.997	0.996	0.999	0.994	0.999	0.994	0.998	0.997
Decision Level 1	7.3	35	30	135	3	0.8	45	33
Bias	0.005	-0.3	0.3	0.1	0.01	-0.018	-0.8	-0.18
Bias 95% Conf. Hi	0.007	0.0	1.0	0.3	0.03	-0.007	0.2	0.04
Bias 95% Conf. Lo	0.003	-0.5	-0.4	-0.2	-0.01	-0.029	-1.8	-0.39
Decision Level 2	7.5	50	80	150	5.8	1.4	180	55
Bias	-0.007	-2.0	0.1	-0.2	-0.04	-0.024	4.3	-1.34
Bias 95% Conf. Hi	-0.004	-1.7	0.6	0.1	-0.03	-0.015	5.4	-1.13
Bias 95% Conf. Lo	-0.010	-2.2	-0.4	-0.5	-0.06	-0.032	3.1	-1.54

Figure 5.3 – Table - Summary results of the Care-Fill vs. Syringe method comparison study

5.6.2 In-house Method Comparison study using capillary samples

This study was performed in-house to establish analytical performance versus the predicate device when using capillary blood samples.

The table in Figure 5.4. below shows the results of the study between the two testing methods: X-i-STAT-CG8 using CLINITUBES and Y-epoc-BGEM using Care-Fill.

	Y: EPOC/CareFill vs X:i-STAT/CliniTube							
	pH	pCO2	pO2	Na	K	Ca	Glu	Hct
N	51	51	52	52	52	52	52	52
Sxx	0.015	1.3	6.7	0.8	0.13	0.020	2.6	0.85
Syy	0.007	1.5	4.5	0.8	0.10	0.014	3.8	0.82
X min	7.357	30.4	56.5	135.0	3.75	1.210	81	36.0
X max	7.478	48.7	100.0	143.5	4.8	1.435	414	51.0
average X	7.425	39.1	76.5	140.5	4.1	1.273	122.2	43.6
average Y	7.403	39.1	82.3	139.2	4.1	1.197	122.4	40.2
average(Yij-Xij)	-0.023	0.5	6.0	-1.0	-0.1	-0.075	0.8	-2.3

Table 5.4 – Table - Average readings and biases for epoc/Care-Fill vs. i-STAT/CLINITUBE

5.7 Summary of Clinical Tests Submitted in Support of Substantial Equivalence

5.7.1 Blood precision when using Care-Fill capillary tubes as delivery method

We performed six (6) precision studies in two (2) POC locations having six (6) different operators testing from three (3) different pools of blood with n=10 replicates per study.

A summary of the results is presented in the table below in Figure 5.5.

Sample	Site	Operator	Param	pH	pCO2	pO2	Na	K	iCa	Glu	Hct
1	Nursery	RN	n	10	10	10	10	10	10	10	10
1	Nursery	RN	avg	7.292	55.2	75.0	132.1	3.2	0.873	52.7	22.1
1	Nursery	RN	SD	0.009	1.2	3.1	1.2	0.05	0.013	1.7	0.6
1	Nursery	RN	%CV	0.1%	2.3%	4.1%	0.9%	1.7%	1.4%	3.2%	2.6%
1	Nursery	POC Tech	n	10	10	10	10	10	10	10	10
1	Nursery	POC Tech	avg	7.289	54.8	72.2	131.4	3.1	0.860	52.3	21.9
1	Nursery	POC Tech	SD	0.006	0.9	1.2	0.5	0.04	0.009	1.5	0.3
1	Nursery	POC Tech	%CV	0.1%	1.6%	1.6%	0.4%	1.4%	1.1%	2.9%	1.4%
2	NICU	RN	n	10	10	10	10	10	10	10	9
2	NICU	RN	avg	7.388	43.0	156.8	138.6	3.2	1.124	143.3	39.1
2	NICU	RN	SD	0.012	1.0	7.1	0.7	0.07	0.028	2.8	0.8
2	NICU	RN	%CV	0.2%	2.3%	4.5%	0.5%	2.2%	2.5%	2.0%	2.0%
2	NICU	RN	n	10	10	10	10	10	10	10	10
2	NICU	RN	avg	7.387	43.8	157.0	139.0	3.2	1.137	144.0	39.8
2	NICU	RN	SD	0.008	0.8	9.1	0.7	0.06	0.025	5.1	1.0
2	NICU	RN	%CV	0.1%	1.8%	5.8%	0.5%	2.0%	2.2%	3.5%	2.6%
3	NICU	RN	n	10	10	10	10	10	10	10	10
3	NICU	RN	avg	7.624	25.5	85.7	149.8	6.7	0.948	222.3	48.0
3	NICU	RN	SD	0.013	0.7	6.3	1.5	0.24	0.012	8.6	1.4
3	NICU	RN	%CV	0.2%	2.8%	7.4%	1.0%	3.5%	1.3%	3.9%	2.9%
3	NICU	RT	n	10	10	10	10	10	10	10	10
3	NICU	RT	avg	7.621	26.0	82.5	150.2	6.8	0.948	222.4	48.0
3	NICU	RT	SD	0.009	0.5	5.4	0.6	0.12	0.008	7.1	0.7
3	NICU	RT	%CV	0.1%	2.0%	6.6%	0.4%	1.8%	0.8%	3.2%	1.4%

Figure 5.5 – Table - Field Trial: Precision Study Summary

5.7.2 Method comparison with predicate device

The method comparison studies were performed in a field trial at a hospital on patient samples of whole blood at the point of care in four (4) locations: NICU, Well-baby Nursery and two (2) different outpatient drawing areas. The testing was performed by five (5) phlebotomists in the outpatient drawing areas, three (3) registered nurses (RN) in the Well-baby Nursery and five (5) registered nurses in the NICU. Patient specimens were 12 adult capillary blood samples and 36 neonatal capillary blood samples. The comparative method was the predicate device.

	Y: EPOC/CareFill vs X:i-STAT/CliniTube							
	pH	**pCO2**	**pO2**	**Na**	**K**	**Ca**	**Glu**	**Hct**
N	47	48	48	48	48	47	48	47
Sxx	0.011	1.2	2.9	0.5	0.15	0.024	1.1	0.89
Syy	0.008	1.4	2.9	0.9	0.15	0.020	1.8	0.75
X min	7.328	26.0	36.0	137.0	3.55	0.93	42.5	31.5
X max	7.552	49.3	91.0	149.5	7.05	1.35	147	61.0
average X	7.408	36.1	52.8	143.3	4.8	1.197	73.1	47.1
average Y	7.387	38.2	54.1	140.8	4.6	1.151	73.6	42.7
average(Yij-Xij)	-0.02	1.5	2.3	-2.5	-0.2	-0.041	0.53	-4.5

Figure 5.6 – Table - Average readings and biases for Epoc/Care-Fill vs. i-STAT/CLINITUBE

In this study, the glucose results coming from neonatal blood specimens were analyzed separately. The summary of this analysis is given in the table in Figure 5.7.

Glucose [mg/dL]	**Y: EPOC/CareFill vs X:i-STAT/CliniTube**
N	36
Sxx	1.3
Syy	2.1
intercept	4.2
slope	0.948
Syx	2.30
X min	42.5
X max	134
R2	0.982
Decision Level 1	45
Bias	1.8
Bias 95% Conf. Hi	2.8
Bias 95% Conf. Lo	0.9
Decision Level 2	180
Bias	-5.2
Bias 95% Conf. Hi	-1.3
Bias 95% Conf. Lo	-9.2

Figure 5.7 – Table - Method Comparison Summary for glucose readings on neonatal capillary whole blood specimens as tested on Y-Epoc/Care-Fill vs. X-i-STAT/CLINITUBE

5.8 Summary of Conclusions Drawn from Non Clinical and Clinical Tests

We conclude from the data presented in section 5.7 that the device performs effectively.

We conclude from the data presented in section 5.8 that the device performs effectively in the hands of the users.

We conclude from the data presented in section 5.7 and 5.8 that the clinical performance of the device when using capillary samples is substantially equivalent to the predicate device: i-STAT Model 300 Portable Clinical Analyzer.

We conclude from the data presented in section 5.8 that that the clinical performance of the epoc glucose test when using neonatal samples is substantially equivalent to the predicate device: i-STAT Model 300 Portable Clinical Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Epocal, Inc.
c/o Roy Layer
2060 Walkley Rd.,
Ottawa, Ontario
CANADA K1G-3P5

MAR 30 2010

Re: k092849
Trade/Device Name: epoc Capillary Blood Samples for use with epoc Blood Analysis System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CEM, CHL, JGS, JFP, JPI, CGA, GIO
Dated: March 23, 2010
Received: March 24, 2010

Dear: Mr. Layer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k092849

Device Name: epoc™ Capillary Blood Samples for use with epoc Blood Analysis System

Indications For Use:

The epoc Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Care-Fill Capillary Tubes are intended for use with the epoc Blood Analysis system and are used for the collection and dispensing of capillary blood samples with epoc Test Cards.

The Blood Gas Electrolyte (BGE) test card panel configuration includes sensors for Sodium - Na, Potassium - K, Calcium - iCa, pH, *p*CO2, *p*O2 and Hematocrit - Hct.

The Blood Gas Electrolyte (BGEM) test card panel configuration includes sensors for Sodium - Na, Potassium - K, Calcium - iCa, pH, *p*CO2, *p*O2, Hematocrit - Hct and Glucose - Glu.

Measurement of sodium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

Measurement of potassium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

Measurement of Ionized Calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092849

Indications for Use

510(k) Number (if known): k092849

Device Name: epoc™ Capillary Blood Samples for use with epoc Blood Analysis System

Indications For Use *(continued)*:

Measurement of pH, *p*CO2, *p*O2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Measurement of Hct distinguishes normal from abnormal states of blood volume, such as anemia and erythrocytosis.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia, and of pancreatic islet cell tumors.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092849